PHARMADERM
Veterinary Division of Altana Inc.

March 24, 1999

Dr. Lonnie W. Luther
Quality Assurance Support Team (HFV-102) Room 387
FDA Center for Veterinary Medicine
7500 Standish Place
Rockville, Maryland 20855

Subject: Pharmaderm, Veterinary Division of Altana, Inc. – Suitability Petition for Miconazole Nitrate Cream 2%.

Dear Dr. Luther,

Please find enclosed a Suitability Petition submitted on behalf of Pharmaderm – Veterinary Division of Altana, Inc. of Melville, NY 11747. Pharmaderm requests consideration of the Suitability Petition to file an ANADA for it's miconazole nitrate 2% topical cream, providing a strength differing from the pioneer product (Mallinkrodt's Conofite® (miconazole nitrate) 2% Cream, approved under NADA 95-183).

You will note that the strength of the generic product is only slightly different than that of the pioneer product. As background economic information regarding the rationale for this Suitability Petition, Pharmaderm proposes to utilize a product of their parent company that is currently manufactured and used in human medicine. This human product is formulated to contain 2% miconazole nitrate rather than 2% miconazole base as used in the pioneer product. It does not appear economically feasible for the sponsor to reformulate and validate separate manufacturing process and controls for a veterinary version of the product. However, the product might be viable if only labeling changes from the human product currently manufactured are necessary and the remainder of the manufacturing process and controls remain usable.

Call if you have any questions.

Sincerely,

Pharmaderm – Veterinary Division of Altana, Inc.

99P-0923

enclosures

CP 1

60 Baylis Road, Melville, N.Y. 11747 1-800-432-6673 Fax: 516-756-7017

SUITABILITY PETITION

1. Identification of Petitioner

This suitability petition is submitted on behalf of Pharmaderm – Veterinary Division of Altana, Inc., 60 Baylis Road, Melville, NY 11747 under section 512(n)(3) of the Federal Food, Drug and Cosmetic Act.

2. Action Requested

The petitioner requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) for a different strength of an approved product. The approved product is Mallinkrodt's Conofite® Cream 2% (miconazole nitrate), approved under NADA 95-183. A copy of the pioneer product labeling is enclosed (Attachment 1).

The ANADA will provide for a product containing 20 mg miconazole nitrate per gram of cream as opposed to the pioneer product which contains 23 mg miconazole nitrate (equivalent to 20 mg miconazole base) per gram of cream. Both products are applied topically as a treatment for fungal infections in dogs and cats. Treatment using the pioneer product is made applying a ¼ inch ribbon of the cream once a day per square inch of lesion for 2 to 4 weeks. The cream is rubbed into the affected site and surrounding area. Dosage and Administration instructions will be made [as necessary] to the amount of the generic cream applied so as to provide approximately the same amount of active ingredient per square inch of lesion as that supplied by a ¼ inch ribbon of the pioneer product.

The ANADA will provide for description, indications, precautions, and warnings identical to the pioneer product. The dosage and administration information will be revised simply to indicate the approximate amount of cream to apply per square inch of lesion.

3. Statement of Grounds

The proposed product contains the same active ingredient and will be labeled with the same indications, precautions, recommended dosage rates, and caution/warnings as the pioneer product. Directions for the amount of cream to administer will be adjusted on the generic product label to recommend topical delivery of an amount of miconazole nitrate (equivalent to that of the pioneer product) to the affected area. The clinical effect of both drugs is expected to be similar.

4. Environmental Impact

The action of submitting and reviewing this Suitability Petition and it's review by FDA-CVM is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR ∋25.30(h) and, to the best of the sponsor's knowledge, no extraordinary circumstances exist.

Unit Carton

50255 Conofite® CREAM, 2% (MICONAZOLE NITRATE)

Directions: _____

_____

_____

_____

LOT : 006215
EXP. : 2/00

50255 NDC 11716-5152-1

Conofite®

CREAM, 2%
(MICONAZOLE
NITRATE)

DOSAGE AND ADMINISTRATION: Use ¼ inch ribbon of cream per square inch of lesion. Rub into affected areas once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

Topical antifungal agent for dogs and cats.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

15 g

Pitman-Moore

Pitman-Moore, Inc.
Mundelein, IL 60060, U.S.A.
Made in Ireland
NADA # 95-163, Approved by FDA

Each gram contains: 23 mg of miconazole nitrate (equivalent to 20 mg miconazole base) in a base containing: cetyl alcohol, stearyl alcohol, butylated hydroxytoluene, white petrolatum, mineral oil, polyoxyl 40 stearate, butylparaben and purified water.

Sold to Veterinarians Only.

23051 PM4

10

Package Insert

FRONT SIDE

Conofite® CREAM, 2%

(MICONAZOLE NITRATE)

DESCRIPTION: CONOFITE (miconazole nitrate) Cream is a synthetic antifungal agent for use in dogs and cats. Each gram contains 23 mg of miconazole nitrate (equivalent to 20 mg miconazole base) in a base containing: cetyl alcohol, stearyl alcohol, butylated hydroxytoluene, white petrolatum, mineral oil, polyoxyl 40 stearate, butylparaben and purified water.

INDICATIONS: CONOFITE (miconazole nitrate) Cream is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis, Microsporum gypseum* and *Trichophyton mentagrophytes.*

PRECAUTION: Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

DOSAGE AND ADMINISTRATION: Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

Apply a ¼ inch ribbon of CONOFITE (miconazole nitrate) Cream once daily per square inch of lesion for 2 to 4 weeks. Rub into infected site and immediate surrounding vicinity. Application is best accomplished using a finger cot or cotton swab. Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

BACK SIDE

HOW SUPPLIED: CONOFITE (miconazole nitrate) Cream in 15 g tubes.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Pitman-Moore
Pitman-Moore, Inc.
Mundelein, IL 60060, U.S.A.

Made in Ireland
NADA # 96-183. Approved by F.D.A.

25030PM3

CONTENTS OF PIONEER PRODUCT TUBE LABEL
(provided due to difficulty photocopying the tube)

TUBE (Scrolling around tube) -

50225 NDC 11716-5152-1

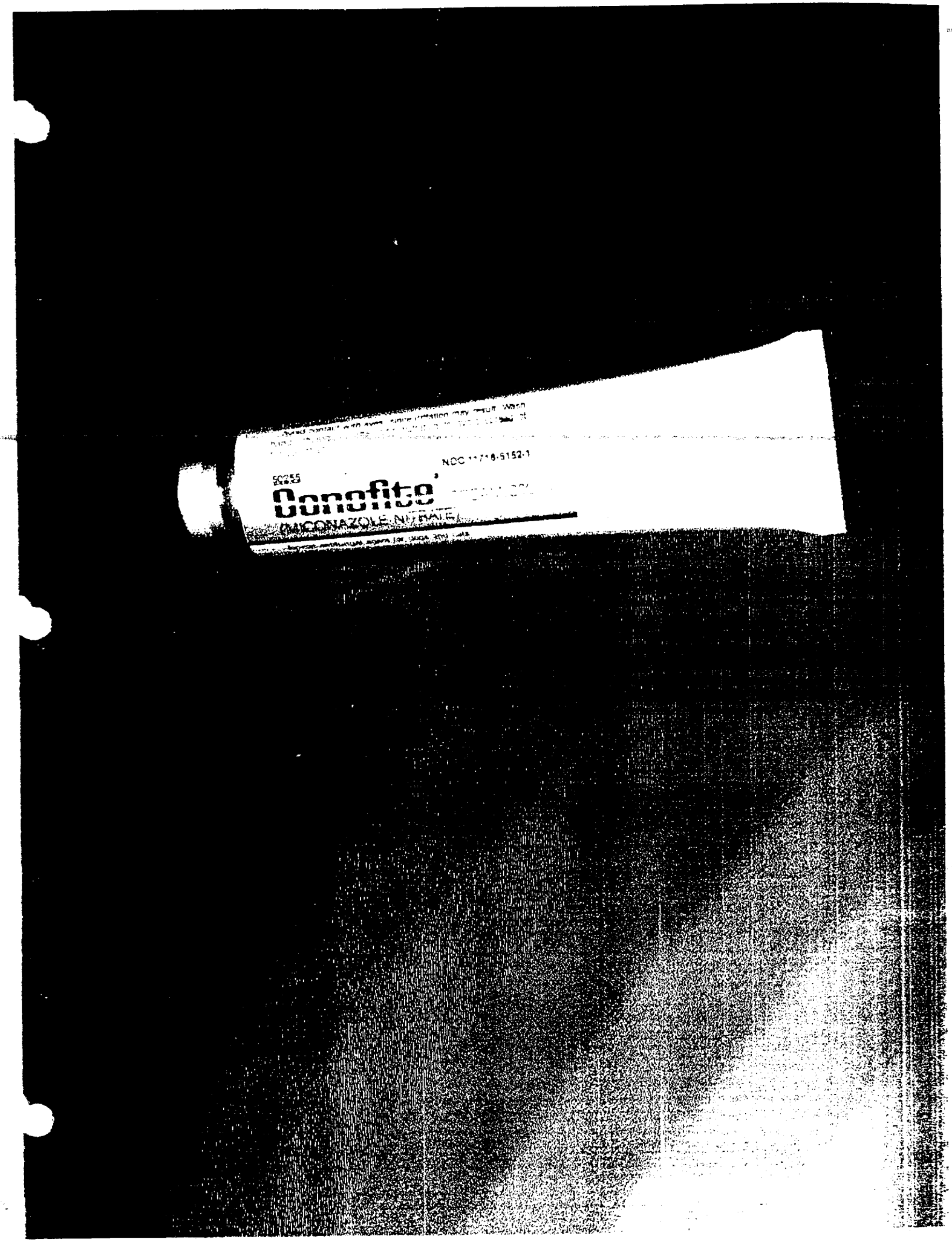
Conofite® Cream 2%
(MICONAZOLE NITRATE)

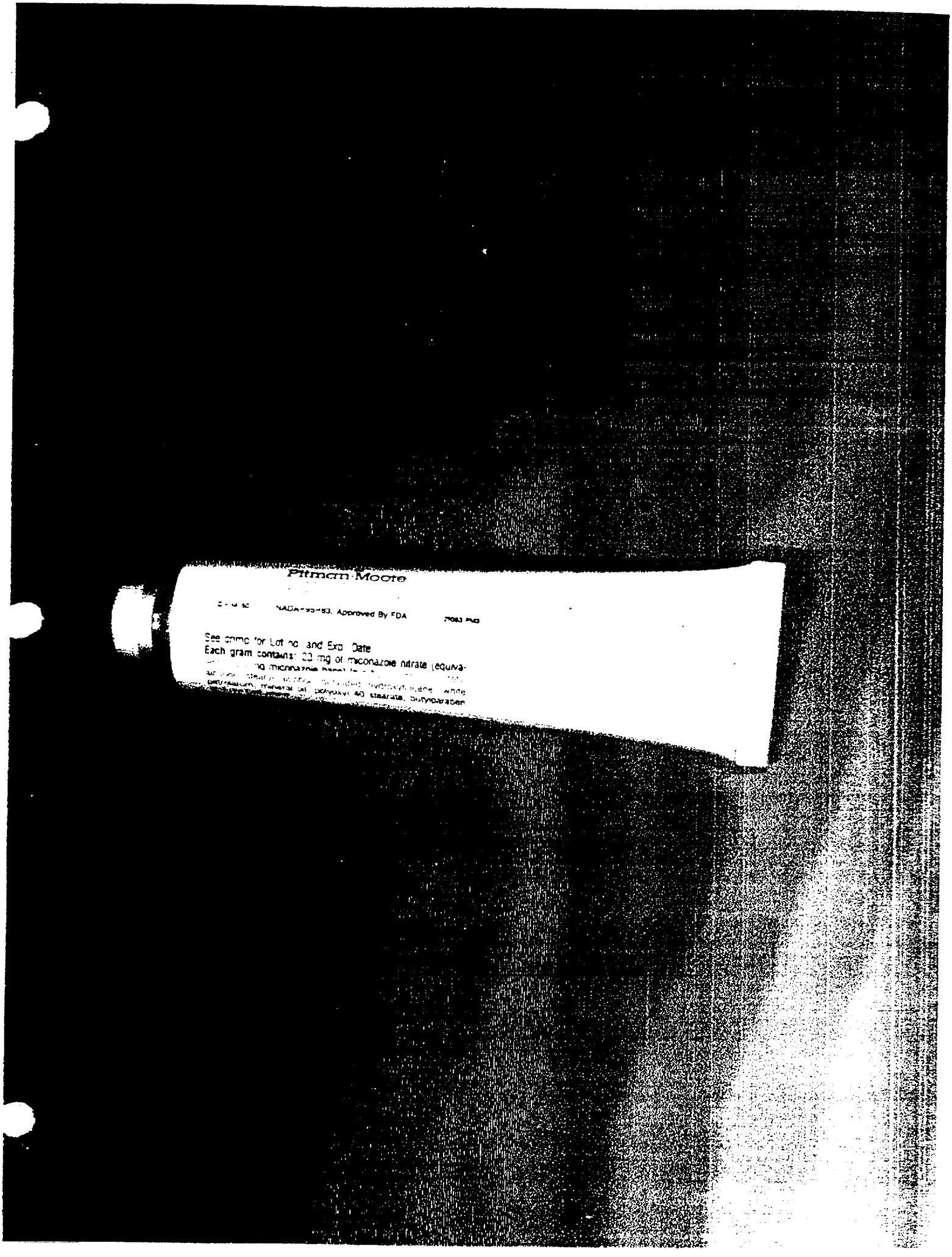
Topical antifungal agent for dogs and cats.
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

15 g

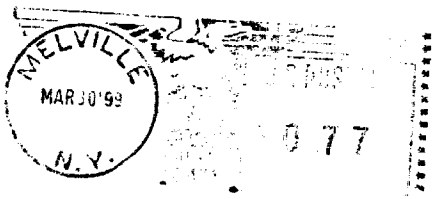
Pitman-Moore
Pitman-Moore, Inc.
Mundelien, IL 60060, USA
Made in Ireland
©P-M '80 ANADA # XXX-XXX, Approved by F.D.A. 21063 PM3

See crimp for Lot no. and Exp. Date
Each gram contains: Each gram contains 23 mg of miconazole nitrate (equivalent to 20 mg miconazole base) in a base containing: cetyl alcohol, stearyl alcohol, butylated hydroxytoluene, whiye petrolatum, mineral oil, polyoxyl 40 stearate, butylparaben and purified water.
DOSAGE AND ADMINISTRATION: Use a ¼ inch ribbon of cream per square inch of lesion. Rub into affected areas once daily for 2 to 4 weeks. See accompanying literature for full directions.
Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.


NDC 11716-5152-1
Conofite
MICONAZOLE NITRATE


Pitman-Moore
NADA-93-483, Approved By FDA
See crimp for Lot no. and Exp. Date
Each gram contains: 23 mg of miconazole nitrate (equiva-

PHARMADERM
A DIVISION OF ALTANA, INC.
ELVILLE, LONG ISLAND, NEW YORK 11747



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